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Application Number

09/095,323

Filing Date

June 10, 1998

First Named Inventor

Michael D. LAUFER

Group Art Unit

3739

Examiner Name

D. Shay

Attorney Docket No.

435712000900

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Firm or Individual Name	Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, California 94304-1018  Richard R. Batt, Reg. No. 43,485
Signature	
Date	October 3, 2002

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Tamara Alcaraz

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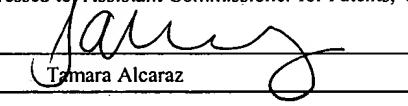
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Tamara AlcarazIN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the application of:

Michael D. LAUFER

Serial No.: 09/095,323

Filing Date: June 10, 1998

For: METHOD AND APPARATUS FOR  
TREATING-SMOOTH MUSCLES IN  
THE WALLS OF BODY CONDUITS

Examiner: D. Shay

Group Art Unit: 3739

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## REPLY BRIEF

Box AF  
Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This Reply Brief is filed under 37 CFR § 1.193(b)(1) and (2)(ii) in response to the Examiner's Answer mailed August 6, 2002 (Paper No. 22) in which a new reference has been applied against the claims. This Reply Brief is for the purpose of replying to new issues raised by the Examiner in the Examiner's Answer under 37 CFR § 1.193(b)(1). Alternatively, if the Examiner's Answer is considered to be reopening prosecution under 37 CFR § 1.193(b)(2), then this Reply Brief is to be considered a request for reinstatement of the appeal under 37 CFR § 1.193(b)(2)(ii) and a supplemental appeal brief.

**I. WO97/37715 IS NOT OF RECORD.**

The Examiner's Answer asserts for the first time during the prosecution of this application a new reference: WO97/37715 to Waksman et al (hereafter "Waksman"). Waksman is not a reference of record in this patent application. Waksman has not been discussed during the prosecution of this application until it was combined with the Clarke patent in the 35 U.S.C. § 103 rejection set forth in the Examiner's Answer.

Although the introduction of Waksman for the first time in the Examiner's Answer is believed to be a new ground of rejection that is otherwise prohibited according to 37 CFR § 1.193(a)(2) *see also* MPEP §1208.01 (8th ed.), Appellant requests that the Board consider the rejection and Appellant's comments here rather than remanding the application to the Examiner. Although Appellant is aware that this is clearly an imposition, Appellant wishes for the Board to consider the matter rather than lose more time by remanding the case. Indeed, this application has been pending since June 10, 1998.

**II. EACH OF THE GROUPS OF CLAIMS IDENTIFIED BELOW IS SEPARATELY PATENTABLE OVER ANY COMBINATION OF THE REFERENCES REFERRED TO IN THE EXAMINER'S ANSWER.**

In view of newly mentioned Waksman, Appellant states that the claims no longer stand or fall together and wishes to regroup the claims as provided herein. Each group of claims, for the reasons set forth below, are separately patentable over the references asserted in the Examiner's Answer. The grouping of the claims is as follows:

Group I: Claims 50, 28-37.

Group II: Claims 29, 30.

Group III: Claims 33-37.

Group IV: Claims 34, 35.

**III. CLAIMS 50, 28-37 (GROUP I) ARE PATENTABLE OVER CLARKE EITHER ALONE OR IN COMBINATION WITH WAKSMAN.**

Although Appellant stands on his arguments set forth in the Appeal Brief, additional comment is appropriate.

As a first matter, U.S. Pat. No. 5,053,033 to Clarke (hereafter "Clarke") alone would not have rendered these claims obvious to one of ordinary skill in this art. Clarke does not disclose or suggest applying energy to airways of the lung as is required by these subject claims. *See* Appeal Brief pages 8-12.

Additionally, the use of "Official Notice" in the Examiner's Answer (at page 3) as a basis for drawing a technological equivalence between UV light treatments of blood vessel smooth muscle cells and treatments with a radioactive source -- the respective treatments described in Clarke and Waksman -- is not permitted except in very limited circumstances. None of the special circumstances is apparent here. Specifically, Official Notice may be taken of facts outside the record that are capable of instant and unquestionable demonstration as being well-known in the art. *See* MPEP § 2144.03 (8th ed.) and the cases cited there. If there is some equivalence, a reference of some kind should be cited. Indeed, the very fact that the Examiner's Answer contains an additional reference in the Section 103 rejection is clear evidence that Clarke alone is insufficient to support the rejection.

The claims of this group are also patentable over Clarke in combination with Waksman. "To establish a *prima facie* case of obviousness, the Board must, *inter alia*, show 'some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" *In re Thrift*, No. 01-1445, 2002 U.S. App. LEXIS 16446 at 12 (Fed. Cir. 2002), *citing In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). *See also, In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002) ("the board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies").

Here, there is no motivation to combine Clarke and Waksman. The Examiner's Answer contains conclusory-type statements as to why one of ordinary skill in the art would make the alleged combination. The Examiner's Answer at page 3 states:

Waksman et al teach the well known equivalence that treatments for blood vessels to prevent excess proliferation [sic] of smooth muscle cells (the paragraph bridging pages 3 and 4) is also useful on trachea and bronchi (see page 5, lines 25-31). Thus it would have been obvious to the artisan of ordinary skill to employ the method in bronchial tissue, since these are equivalents and are composed of smooth muscle cells that respond to the same irradiative treatments as blood vessels, as taught by Waksman et al,

...

This characterization of Waksman is both conclusory and incorrect. Waksman does not state 1.) that treatments for blood vessels are useful on the trachea and bronchi; or 2.) that this equivalence is "well known." In contrast, Waksman mentions at the citation provided in the Examiner's Answer that "[t]he formation of scar tissue by smooth muscle proliferation, also known as intimal hyperplasia, is believed to be a major contributor to restenosis following balloon angioplasty of the coronary artery." Just following (at page 4, beginning at line 4) is the teaching that "[p]rior attempts to inhibit restenosis of coronary arteries have included, among other things, the use of light therapies . . . These therapies have had varying degrees of success, and certain disadvantages are associated with each . . ." A statement that the light therapies have but "varying degrees of success" and "certain disadvantages" does not support an argument that the light emission devices of Clarke are equivalent to the radioactive emission devices of Waksman. It also runs counter to the unsupported "Official Notice" comment provided in the Examiner's Answer.

Furthermore, unlike the Waksman procedure, the independent method claim of this appeal requires that the walls of an airway be irradiated to cause debulking. The term "debulking" is a specific claim limitation not discussed in the rejection. The term "debulking" is found in Appellant's specification at a number of places. For example, it is found at page 6, lines 8-11 which provides: "energy delivery device 10 of the present invention is used to debulk or

reduce the volume of smooth muscle 62 surrounding the airway 60 of an asthma patient and increases the airway diameter for improved air exchange." (emphasis supplied). Additionally, "[t]his treatment does not cause an immediate effect but causes shrinking of the smooth muscle and opening of the airway over time and substantially prevents regrowth." *See* Appellant's application at page 6, lines 18-20. (emphasis supplied). The claims on appeal require debulking or shrinking of the lung tissue by delivering energy.

Waksman, on the other hand, teaches inhibition of restenosis, i.e., the prevention of regrowth rather than the shrinking of tissue. In particular, the Waksman invention specifies inhibiting intimal hyperplasia and reducing the risk of restenosis. *See* Waksman at page 5, lines 15-18. Hyperplasia is the "excessive formation of cells." New American Pocket Medical Dictionary 144 (2nd ed. 1988). Intima is the "internal coat of the blood vessel." *Id.* at 155. Stenosis is "a narrowing." *Id.* at 266. Waksman thus describes and suggests a technique for preventing the buildup or growth of tissue and not a technique for debulking or shrinking the tissue. Waksman does not suggest shrinking or debulking the tissue as required by the claims of this group.

Accordingly, Waksman does not describe or suggest debulking the lung tissue (claims 50, 28-32) or debulking the mucus glands (claims 33-37) by irradiating the walls of an airway. Waksman thus does not supply motivation to modify a method or device such that it will debulk lung tissue because (1) Waksman does not state that the lung or airway tissue is equivalent to the vasculature and (2) Waksman does not disclose or suggest debulking the lung tissue or mucus gland cells. More is required to combine Clarke and Waksman such that the subject claims are unpatentable.

Appellant is also cognizant that Clarke describes an apparatus which may deliver ablative laser radiation. *See* Clarke, col. 3, lines 19-57. Clarke, however, describes tissue ablation in the context of "removing obstructions in a blood vessel by photodecomposition." *See* Clarke, col. 5, lines 15-18. *See also*, claim 4. Clarke suggests using a laser delivery system to remove obstructions such as plaque buildup within the blood vessel and not to debulk the walls

themselves as the subject claims recite. Clarke also does not suggest treating the airway and, as described in Appellant's Appeal Brief (e.g., see pages 8-12 of Appeal Brief), there is no reason to modify the Clarke device/method such that it debulks the airway tissue.

To reiterate, each of Waksman and Clarke teach treatment different than that found in the subject claims. Neither Clarke nor Waksman describes or suggests irradiating the walls of an airway in order to debulk the lung tissue as the subject claims recite. Also, for the reasons set forth above, one of ordinary skill in the art would not have combined the teachings of Clarke and Waksman as urged by the Examiner because Waksman does not state (1) that airways are equivalent to the vasculature (2) that the airways and blood vessels will react equivalently to irradiation, and (3) that the airways (or any tissue) should be "debulked" for therapeutic purposes (or any purpose).

Based on the foregoing, it is submitted that claims 50 and 28-37 are patentable. Reversal of the final rejection, as amended in the Examiner's Answer, is requested.

**IV. CLAIMS 29 AND 30 (GROUP II) ARE SEPARATELY PATENTABLE OVER CLARKE EITHER ALONE OR IN COMBINATION WITH WAKSMAN.**

Claims 29 and 30 (Group II) are patentable over Clarke either alone or in combination with Waksman for the reasons above and in the Appeal Brief. Furthermore, the Group II claims, claims 29 and 30, in addition to containing the claim limitations discussed above, require the irradiating step to be the emission of light. In stark contrast, Waksman is directed to an apparatus using radioactive pellets to emit ionizing radiation such as gamma radiation. *See e.g.*, Waksman at pages 25-26. As noted above, Waksman does not support arguments that application of light energy is equivalent to the application of alpha, beta, or gamma radiation to inhibit restenosis, i.e., the prevention of scar tissue growth.

Given these marked differences between the Waksman technology and the subject matter of the claims of this group, one of ordinary skill in the art would not be motivated to combine the references as urged in the Examiner's Answer. Reversal of the rejection is requested.

**V. CLAIMS 33-37 (GROUP III) ARE SEPARATELY PATENTABLE  
OVER CLARKE EITHER ALONE OR IN COMBINATION WITH  
WAKSMAN.**

The claims in this group are patentable over Clarke either alone or in combination with Waksman for the reasons set forth above and for the reasons set forth in the Appeal Brief. Additionally, the method claims of this group recite that the airway walls are irradiated sufficiently to cause debulking of mucous gland cells. The term "mucous gland cells" is not found within the four corners of either Clarke or Waksman. Neither the final rejection nor the substantial modification of the final rejection in the Examiner's Answer mentions the term "mucus gland cells." Furthermore, Waksman does not suggest debulking airway tissue, much less debulking mucus gland cells. Waksman does not provide the necessary motivation to modify a method/apparatus to debulk the mucus gland cells as the subject claims require. In the absence of any holding in the final rejection relating to the limitations of these claims, the rejection should appropriately be reversed. Such reversal is requested.

**VI. CLAIMS 34-35 (GROUP IV) ARE SEPARATELY PATENTABLE  
OVER CLARKE EITHER ALONE OR IN COMBINATION WITH  
WAKSMAN.**

Claims 34-35 are separately patentable over Clarke either alone or in combination with Waksman for the reasons listed above and for the reasons found in the Appeal Brief. These claims additionally require the treatment of mucous gland cells by emitting light energy. Neither of the terms "mucous gland cells" nor "emitting light" are mentioned in Waksman, much less debulking mucus gland cells by emitting light at specific wavelength ranges. The specific wavelength ranges required by the claims are not found in either the final rejection or the modified final rejection in the Examiner's Answer. Consequently Waksman does not provide the necessary motivation to modify a method/apparatus to debulk the mucus gland cells as the subject claims require.

## VII. CONCLUSION

Based on the foregoing, the above referenced groups of claims (groups I, II, III, and IV) are separately patentable over any combination of the references cited in the Examiner's Answer. The rejection of claims 28-37 and 50 should be reversed.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **435712000900**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: October 3, 2002

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